



Is the glucose management of your most critical patients Best-in-Class?

To find out, take this simple quiz.

The ACCU-CHEK[®] Inform blood glucose monitoring system

- 1. What is a recommended blood glucose range for achieving tight glycemic control in critical care patients?¹**
 - a. 80-110 mg/dL
 - b. 60-100 mg/dL
 - c. 70-140 mg/dL
 - d. less than 180 mg/dL

a. 80-110 mg/dL
- 2. How often should blood glucose levels be tested when implementing an intensive insulin protocol?²**
 - a. Once every four hours for 24 hours
 - b. Once every two hours for 12 hours
 - c. Once every hour until an 80-110 mg/dL level is achieved
 - d. Once every shift until patient is taken off insulin

c. Once every hour until an 80-110 mg/dL level is achieved
- 3. Frequent blood glucose testing can increase the number of misidentified patient results. What is the recommendation for improved accuracy of patient identification?**
 - a. Chart stickers
 - b. Nurse training
 - c. Electronic Medical Records
 - d. Two patient identifiers

d. Two patient identifiers³
- 4. Controlling blood glucose with intensive insulin therapy can provide what clinical benefits?**
 - a. Decrease in post-operative infections and sepsis¹
 - b. Reduction in hospital mortality by 34%¹
 - c. Length of stay in the ICU cut by half⁴
 - d. Greater cost savings with improved patient care⁵
 - e. All of the above

e. All of the above
- 5. What key requirements help achieve and maintain tight glycemic control?**
 - a. Clinical accuracy across a wide hematocrit range, with no interference from pO₂ or 125+ medications/metabolites
 - b. Actionable information from meter to LIS and EMR, allowing simplified protocol review
 - c. Patient safety enhancements by improving accuracy of patient IDs
 - d. Consideration for the comfort of patients who require frequent testing
 - e. All of the above

e. All of the above

To help you provide Best-in-Class care for critical patients, ACCU-CHEK product solutions from Roche Diagnostics are the correct choice for a tight glycemic control program.

For more information, visit www.glycemiccontrol.net, contact your Roche Diagnostics representative, or call the ACCU-CHEK Tight Glycemic Control Info Line at 1-888-837-8212.

¹ Van den Berghe, G., et al. Intensive Insulin Therapy in Critically Ill Patients. *N Engl J Med.* 345(19):1359-67, 2001.
² Goldberg, P., et al. Implementation of a safe and effective insulin infusion protocol in a medical intensive care unit. *Diabetes Care.* 27(2):461-467, 2004.
³ 2005 Hospitals' National Patient Safety Goals. www.jcaho.org
⁴ Umptierrez, G., et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab.* 87(3):978-982, 2002.
⁵ Data on file at Roche Diagnostics.

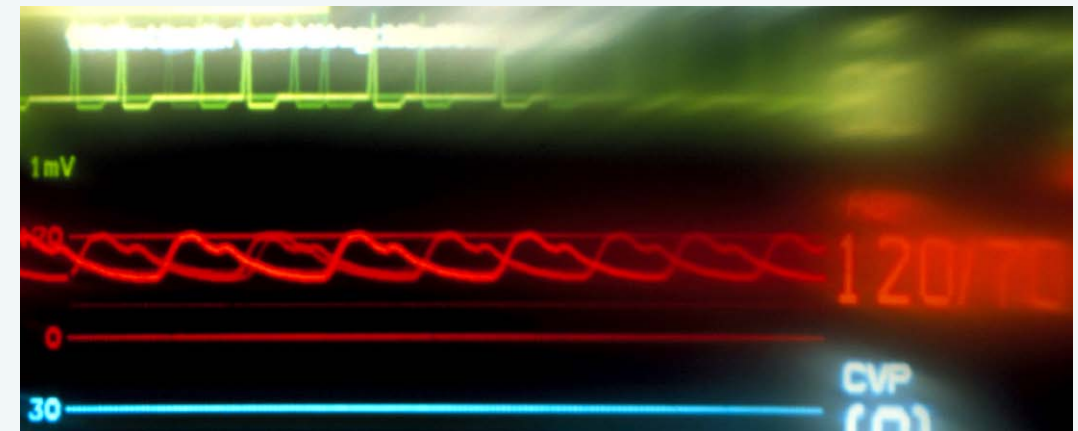
ACCU-CHEK, ACCU-CHEK INFORM, COMFORT CURVE, and SAFE-T-PRO are trademarks of Roche.

© 2005 Roche Diagnostics. All rights reserved. 330-26340-0705.

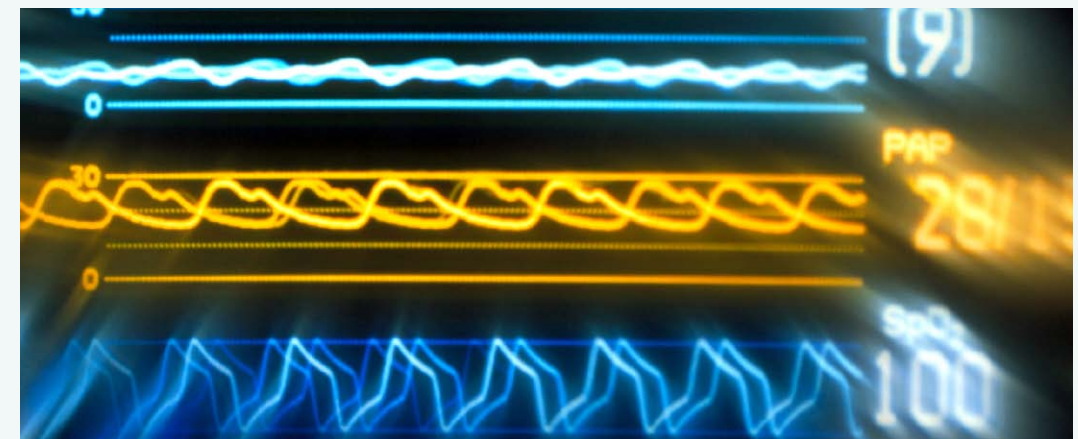
Temperature and pulse, move over. Blood pressure and breathing, prepare for company. A new vital sign may soon join your ranks. And many critical care patients could be the lucky beneficiaries.

What new sign is so "vital" to treatment outcomes that it could actually shake the status quo in healthcare? Blood glucose.

Preparing for



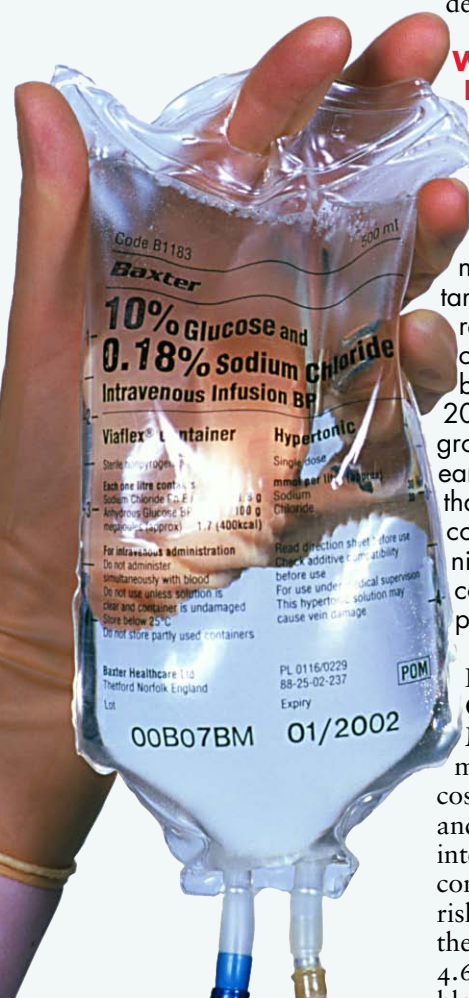
the Next Vital Sign:



Blood Glucose Level

Not exactly new, you say. True, but the growing understanding of its critical role in outcomes, especially in surgical intensive care, is nothing short of revolutionary.

By Stanley A. Nasraway, Jr., M.D.



More specifically, the demonstrated ability of insulin and tight glycemic control to reduce SICU infections and mortality in dramatic ways has some evidence-based-medicine advocates convinced it's the most important advance in critical care medicine in three decades.

What's so Vital About Blood Glucose?

Hyperglycemia has been a known metabolic response to injury, severe illness, and surgery for some time. So, naturally, blood glucose target ranges have been relaxed in many critical care units. But groundbreaking research in 2001 helped to confirm a growing suspicion – and earlier research findings – that blood glucose levels could, in fact, have a significant impact on outcomes with acutely ill patients.

In a Belgian surgical ICU, Greet Van den Berghe, M.D., Ph.D., found that maintaining a blood glucose level between 80 mg/dL and 110 mg/dL through intensive insulin therapy by continuous infusion reduced risk of death by 42% during the ICU stay: from 8% to 4.6%. (The control group blood glucose level was 180 mg/dL–200 mg/dL, fairly standard protocol for a surgical ICU.)

The key factor for the improved outcomes appeared to be a decreased likelihood of systemic infection: the incidence of death due to sepsis-related multiple organ failure dropped the most.

Another striking aspect of the study was that the reduction was the result of a widely available and relatively inexpensive treatment modality: insulin. So, as financial and outcome-related pressures began to grow in the hospital setting, so did interest in the role of blood sugar, and in confirming Van den Berghe's initial results.

The most significant follow-up research to date may be a retrospective intensive insulin protocol study conducted by James Krinsley, M.D., at a community hospital medical-surgical ICU in Stamford, CT. Krinsley found that maintaining blood glucose levels between 80 mg/dL and 140 mg/dL resulted in a 29% reduction in hospital mortality for the protocol group. Other studies, including a follow-up investigation by Van den Berghe, showed that tight glycemic control reduced length of stay and that it was indeed the tight glycemic control, not just the use of insulin, that was responsible for improved outcomes.

Perhaps even more important, growing evidence indicates that the benefits of tight glycemic control could extend well beyond patients with diabetes, improving morbidity and mortality in all critically ill patients.

The ramifications for hospitals are significant: The stage is now set to adopt comprehensive blood glucose protocols in ICUs across the country, but adopting anything “comprehensive” in the hospital setting doesn't come easy.

Encountering Insulin Resistance

With the opportunity for hospitals to have a major impact on critical care outcomes at a relatively low cost, the choice to adopt a tight glycemic protocol would seem obvious. But change is never easy, and resistance comes in many forms.

Some resistance is understandable, and raises genuine financial and procedural questions. Adopting a new protocol that may require hourly blood glucose testing across an entire ICU – or an entire campus – can require a significant investment of staff time, education, money, and other resources. And there is legitimate concern about potential hypoglycemia-related complications from an intensive insulin infusion program.

Other types of resistance are rooted more in tradition (such as not wanting to change the way things have always been done), or they're tied into common misconceptions (for example, the belief that achieving normal blood glucose values among critical care patients is impossible) and not really that important.

Even in terms of simple logistics, other significant questions loom: Which protocol is the best one? What is the ideal blood glucose target?

The solutions are not always easy to find or to implement. But the ramifications of reduced mortality and length of stay for patient care – not to mention healthcare financials – are

so substantial that it's just a matter of time before every ICU will need to address the issue of tight glycemic control.

How to Develop an Effective Protocol

Fortunately, the experience of several pioneering institutions around the country has shown that following a few guidelines can help make implementing a glucose protocol easier and more effective.

Make Education a Priority

In the hospital setting, resistance to change usually happens because the value of change is not clear. Education about the improved outcomes from tight glycemic control has to play a key role in the development, testing, and rollout of a protocol. With clinicians typically being highly motivated by data, presenting the available evidence can be a persuasive approach. The development of an outcomes-oriented quality improvement program within the hospital will help to simplify this task.

Much of the initial resistance to a tight glycemic control protocol, for example, often comes from the nursing staff. This is no surprising because their routines will be disrupted the most by insulin drips and hourly glucose measurements. But they also tend to be highly motivated by improved outcomes and are in the best position to see immediate feedback when, for example, they adjust an insulin infusion. This kind of feedback and education on the impact

tight glycemic control can have on patient care and outcomes can go a long way in softening resistance to change.

And the change in routine may not be that significant. In Stamford, Dr. Krinsley found that, even though nurses had been enculturated to not treat high blood glucose, the number of nursing hours did not increase as a result of a new protocol.

At Yale New Haven Hospital, Mark Siegel, M.D., the director of the medical ICU, also found that nurses were overly concerned about possible hypoglycemia when patient blood glucose levels went below 100 mg/dL. To counter that, an endocrinologist colleague, Philip Goldberg, M.D., had the staff guess their own blood sugar and then let them see how low it really was with a fingerstick. Under the hospital's protocol, Dr. Siegel says, patients are monitored so closely that symptomatic low blood sugar rarely happens.

The combination of active leadership by the ICU director, education, and good communication between members of the ICU healthcare team goes a long way in reducing resistance to intensive protocol implementation.

Evaluate resources and economic impact

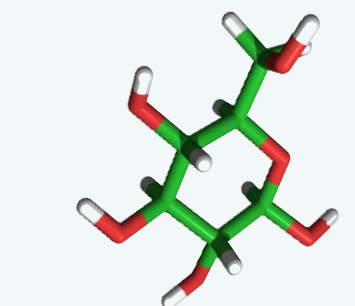
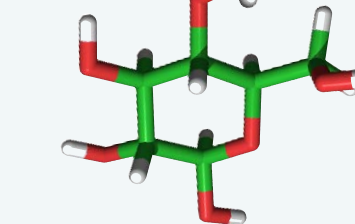
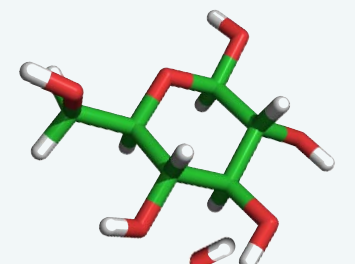
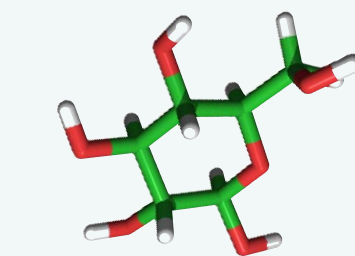
Beyond labor issues, there are questions about the financial impact of a new protocol and the availability of resources to implement it: sufficient number of meters for hourly point-of-care testing, test strip budgets, and

the impact on pharmacology for insulin mixes, etc.

When a new glucose control protocol was adopted at Florida Hospital in Orlando, for example, nurses mixed their own insulin drips. Later the hospital decided to have the pharmacy mix all the insulin infusions at a standard concentration. “There was a feeling from the lab that increased testing is going to impact the budget,” says Harold Walden, point-of-care coordinator. But in the final analysis, we determined that the medicine was more important than the budget.”

In our own Surgical ICU at Tufts-New England Medical Center, we recently increased the number of blood glucose meters to one at every bedside to increase convenience and reduce the “hassle” factor for each nurse. Doing this raises “buy-in” by the nursing staff and also sends a subliminal message that tight glycemic control is so important that each SICU patient deserves his or her own meter.

In the long run, adopting a tight glycemic control protocol should have very positive economic impact. According to Samuel Crocket, M.D., endocrinologist and director of the Diabetes Center at Florida Hospital, when you factor in the costs of surgical infections, this kind of protocol can cut the average cost of long-term care for a diabetic patient in half.



Use a Balanced Multiple-Discipline Approach

Implementing a rigorous protocol like tight glycemic control can be nearly impossible without a broad team effort, but a team approach can also have its drawbacks.

On the positive side, utilizing a team to conceive, develop, and roll out a new protocol helps ensure buy-in from all disciplines and helps guarantee that the protocol will be supported and implemented on a consistent, day-by-day basis.

At Florida Hospital, for example, the protocol team included representation from a broad base of health-care backgrounds, including nutritionists, educators, frontline care, intensivists, pharmacy, and the medical director of the QI process improvement team. A few individuals primarily drove the team, but the protocol's overall success stemmed from the team approach.

On the other hand, relying on a team approach to implement the day-to-day aspects of a protocol can hinder nursing staff and drag the process into a quagmire of inefficiency. According to Dr. Van den Berghe, implementing a successful tight glycemic control program takes more than a protocol; it requires a very motivated and empowered team. "In our experience, what makes it work is to trust the nurses to be responsible," she says. Dr. Krinsley notes that, at

Stamford Hospital, nurses are empowered to make bedside decisions using the protocol as a guide, but also to be more proactive and use their own initiative.

Plan for Logistical Challenges

While frontline patient care staff members need to be empowered to make decisions and take initiative, the inherent nature of a protocol requires standardization of practices, which can raise a few procedural issues.

Managing data is one example. It's critical to have consistent data collection and good data management to get timely, accurate feedback on the effectiveness of treatment regimens and to make effective modifications. With convenient access to a reliable database, you can get a clear, quantitative picture of how changes in care affect outcomes. Continuing to measure outcome changes as you implement or modify a protocol allows you to conduct effective quality performance improvement efforts.

Another logistical challenge in implementing a protocol is to ensure tight glycemic control during patient care transition, such as from the ICU to a ward. If the treatment regimen shifts from insulin infusion to subcutaneous insulin and diet, for example, it's important to make sure all the appropriate caregivers, such as dietitians, are on board with the protocol and are familiar with its goals and implementation. It's also important to have good communication between the critical and the noncritical care teams so the transition can be smooth and effective.

Although the development of a consistent protocol across disciplines and areas

is essential, making it user-friendly can help ensure that it's received well and implemented properly. Providing a blood glucose meter at every bedside, as we did at the Tufts-New England Medical Center SICU, is just one example. Another way to be sensitive to nursing workload issues is to determine how often, and by what means, the meters should be connected to the data management system to make the process as convenient as possible.

Getting Started: Protocol Guidelines

Finally, for some critical care units still evaluating the idea of a tight glycemic control protocol, one particular issue may pre-empt all the others: Which protocol? There is no one-size-fits-all answer, but helpful guidelines are available in a position statement published by the American College of Endocrinology in December 2003. It provides a good basic overview of outcome-based evidence for tight glycemic control and recommends specific glycemic targets. It also discusses factors to consider in determining what methods to use to regulate glucose levels.

The specific methods you establish are not as important as the general implementation of tight glycemic control. It's clear that the conventional relaxed approach to hyperglycemia in ICU patients has profound medical consequences. Developing a protocol to bring blood glucose targets closer to normal levels is virtually guaranteed to improve mortality and morbidity, and reduce length of stay – in other words, improve outcomes for the patient and hospital alike.

References

- American College of Endocrinology. American College of Endocrinology Position Statement on Inpatient Diabetes and Metabolic Control. *Endocr Pract.* 2004;10 (No. 1).
- Finney SJ, Zekveld C, Elia A, et al. Glucose control and mortality in critically ill patients. *JAMA.* 2003; 31:634-635.
- Informal Panel Discussion, 2005.
- Krinsley JS. Association between hyperglycemia and increased hospital mortality in a heterogeneous population of critically ill patients. *Mayo Clin Proc.* 2003;78:1471-1478.
- Krinsley JS. Effect of an intensive glucose management protocol on the mortality of critically ill adult patients. *Mayo Clinic Proc.* 2004;79:992-1000.
- Krinsley JS. Personal communication, 2005.
- Lazar HL, Chipkin SR, Fitzgerald CA, Bao Y, Cabral H, Apstein CS. Tight glycemic control in diabetic coronary artery bypass graft patients improves perioperative outcomes and decreases recurrent ischemic events. *Circulation.* 2004;109:1497-1502.
- Krinsley JS. Reported in: ICUs tighten belts on blood glucose levels. *CAP Today* 2005 (Feb.).
- Siegel M. Reported in: ICUs tighten belts on blood glucose levels. *CAP Today* 2005 (Feb.).
- Van den Berghe G. Reported in: ICUs tighten belts on blood glucose levels. *CAP Today* 2005 (Feb.).
- Van den Berghe G, Wouters PJ, Bouillon R, et al. Outcome benefit of intensive insulin therapy in the critically ill: insulin dose versus glycemic control. *Crit Care Med.* 2003;31:359-366.
- Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med* 2001; 345:1359-1367.

Pacesetting With Point-of-Care Testing (POCT): Wellness Connectivity

By Kathleen Hudson

How can we best arrive at clinical treatment answers requiring a human sample to be analyzed during the clinical decision-making process?

Improving technology provides quicker results and connectivity with ever-expanding point-of-care testing (POCT) applications. Recent advances in computer chip technology have made possible more direct and convenient answers to clinical questions at the point of care. POCT applications have expanded to include bedside testing, alternate-site testing, decentralized testing, and testing outside the usual laboratory. With the inevitable trend toward a shared responsibility in health prevention, illness, and chronic disease management, including palliative and terminal care, the "bedside" has expanded to include schools, ambulance/water/air healthcare transport vehicles, hospitals, homes, clinics, workplaces, and treatment centers. Today, POCT is frequently included in community screening booths at shopping malls.

As with any device used in clinical decision-making, the population using the apparatus must be a fundamental consideration in determining design and complexity. As the number of elderly and chronically ill increase, home POCT markets are rapidly expanding and becoming more important. Neighborhood pharmacies are another arena for expanded POCT use, heightening levels of self-monitoring and wellness potential.

POCT devices are available for patient care across the life span, from newborns to the elderly. Healthcare professionals use POCT devices in car-

ing for patients in all phases of the health continuum, including screening, diagnostics, and treatment. The three levels of POCT devices include small bench-top analyzers (smaller replicas of laboratory equipment), handheld devices that are outwardly simple yet internally complex, and single-use, noninstrumented devices, such as pregnancy test kits, are usually inexpensive, disposable, and readily available to consumers in many stores.

Some POCT is specifically designed for screening and may require follow-up with more thorough tests from a main hospital laboratory. In some unstable or high-risk situations, the patient's samples are routed to a main laboratory instead of, or in addition to, using POCT. The main laboratory may provide a higher level of required precision or confirm previous results. An example of this would be for a positive employee drug screen, which could trigger an automatic employment termination. In these instances, the sample integrity trail becomes extremely important because of the potential for litigation if there is doubt in the soundness of either the process or organizational confidentiality. Certainly for some POCT, related issues become important in overall program planning.

